

### **REMARKS**

Claims 1-11 are currently pending.

#### **Claim Rejections - 35 U.S.C. § 103(a)**

In the Non-Final Office Action mailed December 28, 2007, the Examiner rejected claims 1-11 under 35 U.S.C. § 103(a) as being unpatentable over Thomas (U.S. Patent No. 5,811,446) in view of Blackburn *et al.* (U.S. Patent No. 4,980,163, hereinafter “Blackburn”). Applicant respectfully traverses the rejection.

The Examiner asserts that Thomas teaches a method of treating blepharitis comprising administering to a subject in need of such treatment a therapeutically effective amount of a ‘broad range antibiotic’ and a saline solution carrier. The Examiner states that, although Thomas does not teach the broad range antibiotic duramycin Blackburn teaches broad range antibiotic compositions comprising duramycin which target *Staphylococcus aureus*. Therefore, the Examiner asserts one of ordinary skill in the art would have been motivated to modify the method of Thomas to use the duramycin containing composition taught by Blackburn because Thomas teaches a method of treating blepharitis using broad range antibiotics. Further, the Examiner asserts there would have been a reasonable expectation of success given that both Thomas and Blackburn teach that antibiotic compositions are preferably effective against *S. aureus*.

Applicants respectfully disagree with the Examiner’s reading of these references. Thomas does *not* teach a method of treating blepharitis comprising administering a therapeutically effective amount of a ‘broad range antibiotic’ composition. Thomas teaches a method of treating sequelae of degenerative eye disease, such as inflammation, using a *histidine* composition (Column 3, lines 40-43, Column 4, lines 55-67) to decrease inflammation. In certain embodiments, antibiotics are coadministered, but these are not taught as being useful for treatment of any dry eye diseases. Contrary to the Examiner’s assertion, Thomas does not teach or suggest the use of a broad range antibiotic composition for treating blepharitis. Indeed, Thomas directs one of skill in the art away from the use of any antibiotics to treat dry eye diseases, stating that many antibiotics are not well-tolerated, give rise to toxicities, or are of only moderate efficacy (Column 3,

lines 12-14). Therefore, one of ordinary skill in the art would not be motivated to use any antibiotics, and in particular the claimed antibiotics for treating blepharitis based on the teaching of Thomas.

Blackburn does not remedy the deficiencies of Thomas. Blackburn describes a composition comprising lysostaphin and a lanthionine containing bacteriocin for use as an antibiotic composition. Blackburn does not teach a method of treating dry eye disease using antibiotics. As evidenced by Thomas, the use of antibiotics in treatment of ocular diseases was recognized as unpredictable (see Column 3, lines 12-14). Therefore, absent some showing to the contrary by Blackburn, one of skill in the art would not have a reasonable expectation of successfully using a composition such as described in Blackburn to treat any ocular condition, more specifically dry eye disease. Without an expectation of success in the combination, one of ordinary skill in the art would not be motivated to substitute the histidine compositions as described in Thomas with the composition as taught by Blackburn, in order to derive the presently claimed invention. For at least the foregoing, applicant submits the rejection under 35 U.S.C. § 103(a) has been overcome and respectfully request that it be withdrawn.

### **Claim Rejections - Double Patenting**

In the Non-Final Office Action mailed December 28, 2007, the Examiner provisionally rejected claims 1-11 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending U.S. Application No. 11/123,436. Because the obviousness-type double patenting rejections are provisional, Applicants request that the rejections be held in abeyance pending the determination of patentable subject matter. Applicant suggest that if all other rejections are overcome, it is appropriate to withdrawn the provisional double-patenting rejection and allow the instant application to issue, as directed by the MPEP (see MPEP, Chapter 800, Section 804).

### **CONCLUSION**

The foregoing is submitted as a full and complete response to the Final Office Action mailed December 28, 2007, and early and favorable consideration of the claims is requested. If the Examiner believes any informalities remain in the application that may be corrected by Examiner's amendment, or there are any other issues which can be resolved by telephone interview, a telephone call to the undersigned agent at (404) 572-2447 is respectfully solicited. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 11-0980.

Respectfully submitted,

**/F. Brent Nix/**

F. Brent Nix  
Reg. No. 59,004

KING & SPALDING LLP  
1180 Peachtree Street, N.E.  
Atlanta, Georgia 30309-3521  
Telephone (404) 572-4600  
Facsimile (404) 572-5134